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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,002	10/08/2003	Pierre-Etienne Chabrier De Lassauniere	427.057-I	7432
47888	7590	06/01/2006	EXAMINER	
HEDMAN & COSTIGAN P.C. 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036				ANDERSON, REBECCA L
ART UNIT		PAPER NUMBER		
				1626

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/681,002	CHABRIER DE LASSAUNIERE ET AL.	
	Examiner	Art Unit	
	Rebecca L. Anderson	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 03 May 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 35-43 and 45-48 is/are pending in the application.
 - 4a) Of the above claim(s) 36 and 47 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 35,37-43,45,46 and 48 is/are rejected.
- 7) Claim(s) 38-40,42,43,45 and 48 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. 10/089,993.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/8/2003.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Claims 35-43 and 45-48 are currently pending in the instant application. Claims 35, 37-43, 45, 46 and 48 are rejected, claims 38-40, 42, 43, 45 and 48 are objected and claims 36 and 47 are withdrawn from consideration as being for non-elected subject matter.

Election/Restrictions

Applicant's election of the products of Group II and the further election of the compound of example 1 in the reply filed on 3 May 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Therefore, as stated on pages 4 and 5 of the restriction, **the elected invention for search and examination** is the products of the formula (I)G in racemic, enantiomeric form or any combination of these forms, in which **Het** is a heterocycle with 5 members consisting of 2 heteroatoms and such that formula (I)G corresponds exclusively to one of the following sub-formulae: (I)G1 or (I)G2 in which **A** is as found in claim 35 in which **Q** is OR22 and **R22** is hydrogen and **R19**, **R20** and **R21** are hydrogen or alkyl; **X** is –S–; **R1** and **R2** are hydrogen; **B** is hydrogen; **Ω** is NR46R47; **R46** and **R47** are hydrogen or alkyl; and **n**, is 0 to 6; and additionally the specific compounds and pharmaceutical compositions of claims 40, 42, 43 and 48 which are not within the formula (I)G of claim 35.

The remaining subject matter of claim 45 that is not drawn to the above elected invention and the subject matter of claims 36 and 47 stands withdrawn under 37 CFR 1.142(b) as being for non-elected subject matter. The remaining products which are not within the elected invention, which are independent and distinct from the elected invention and do not have unity with the elected compound and are therefore withdrawn by means of a restriction requirement within the claims are, for example, the compounds of the formula (I)G or (III)G wherein the compound is (III)G3 or (III)G4 or wherein A is selected from the group a), b), d) or e) or wherein Q is hydrogen or phenyl, SR22, NR23R24; or X is NR38; or R1 and R2 are heteroarylalkyl; or B is a carbocyclic aryl; or Ω is OR48, etc.

The above mentioned withdrawn compounds, which are withdrawn from consideration as being for nonelected subject matter, differ materially in structure and composition from the compounds of the elected invention. The withdrawn compounds differ from those of the elected invention and are chemically recognized to differ in structure and function. This recognized chemical diversity of the compounds can be seen by the various classification of these compounds in the U.S. classification system. Therefore, again, the compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition and have been restricted properly as a reference which anticipated but the elected subject matter would not even render obvious the non-elected subject matter.

These withdrawn compounds are independent and distinct from the elected invention and do not have unity with the compound elected and are therefore withdrawn by means of a restriction requirement within the claims.

The requirement is still deemed proper and is therefore maintained.

Claim Objections

Claim 45 is objected to as containing non-elected subject matter. Claim 45 presented drawn solely to the elected invention identified supra as **the elected invention for search and examination** would overcome this objection.

Claims 40 and 42 are objected to because of the following informalities: Claims 40 and 42 are objected to as the Markush expression in the claim is improper, i.e. the claim should read –selected from the group consisting of the following compounds: A; B; C;.....and Z; or a salt thereof--, not as instantly written as –selected form the group consisting of the following compounds; A; B; C;....; Z; and salts thereof. Specifically, claims 40 and 42 should include the term “and” between the last two mentioned compound names. Appropriate correction is required.

Claim 40, 42, 43 and 48 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Specifically, the claims include specific named compounds, for example, butyl 2-(4-[1,1'-biphenyl]-4-yl-1H-imidazol-2-yl)ethylcarbamate, which are not within the subject matter of the parent claims. Therefore, the claims fail to further limit the subject matter of the parent claims as the claims includes subject mater outside the parent claims

subject matter. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 43 and 45 are objected to because of the following informalities:

Specifically, claims 45 and 45 are dependent upon cancelled claims. Appropriate correction is required, such as rewriting the claims in independent form presented drawn solely to the elected invention for search and examination.

Claim(s) 38 and 39 is/are objected to for being substantial duplicates of the one another. When two claims in an application are duplicates, or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a substantial duplicate of the allowed claim. M.P.E.P. 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41, 45 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claims 41, cancelled claim 44 and claim 47 contain multiple instances of the term “general”, such as “general formula (I)G” which renders the claims indefinite. The use of the term “general” in phrases such as “general formula” renders the claims indefinite since the term general is defined as, for example, as involving only the main features and not limited in scope (Webster’s II

New Riverside University Dictionary, 1984). Therefore, it is unclear what compounds are encompassed by the instant claims since the claims are directed to the general formula (I)G or the general formula (III)G, which is not limited to the compound described as formula (I)G or (III)G but also includes other compounds outside the scope of the compounds of the formulas. It is suggested that the term "general" be deleted from all instances of the claims to overcome this rejection.

Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, this claim includes the term "comprising" in the definition of the products which renders the products indefinite as the term comprising is considered open-ended language and therefore is including additional subject matter in the compounds that is not described in the instant specification and is not particularly pointed out or distinctly claimed. A claim to a chemical compound cannot be open-ended, but must be claimed with precision. For example, a heterocycle with 5 members comprising 2 heteroatoms can be read to include additional heteroatoms, however, the identity of the additional heteroatoms how to determine the identity of the heterocycle is not pointed out or distinctly claimed. This rejection can be overcome by amending all instances of the terms "comprising" to the phrases "consisting of".

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis

added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 40, 42, 43 and 48 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 40, 42, 43 and (39 and 49) of copending Application No. 10/915001 (US Pre-grant publication 2005/0038087). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. Specifically, the conflicting claims are claiming the exact same chemical species as applicants' instant claims.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 35, 37-39, 45 and 46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3 and 6 of U.S. Patent No. 6,586,454. Although the conflicting claims are not identical, they are not patentably distinct from each other because conflicting claim s3 and 6 are directed to compounds which are within the scope of applicants' instantly claimed invention or are homologs, i.e. when R1 and R2 are alkyl of 1 to 6 carbon atoms (conflicting claim 6) or positional isomer, i.e. when claim 3 does not have the tert-butyl groups on the phenol in positions 2 and 6. However, these compounds render obvious applicants' instantly claimed invention as to those skilled in chemical art, one homologue is not such an

advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members. Also, the instant claimed compounds would have been obvious because one skilled in the art would have been motivated to prepare homologs of the compounds taught in the reference with the expectation of obtaining compounds which could be used in pharmaceutical compositions. Therefore, the instant claimed compounds would have been suggested to one skilled in the art. Lastly, nothing unobvious is seen in substituting the known claimed isomer for the structurally similar isomer since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. Since conflicting claims 3 and 6 anticipate or renders obvious applicants' instant claimed invention as the conflicting claims are directed to specific compounds within applicants' instantly claimed product claims or which render obvious applicants' instantly claimed product claims, applicants' product claims are therefore provisionally rejected on the ground of nonstatutory obviousness-type double patenting.

Claims 40, 42, 43 and 48 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 44 of copending Application No. 10/333,566. Although the conflicting claims are not identical, they are not patentably distinct from each other because conflicting claim 44 is claiming specific compounds within applicants' instantly claimed compounds which anticipate applicants' instantly claimed invention of claims 35, 36, 37, 40, 41, 44, 44, 48, 49 and 50, such as butyl (4-(1,1'-biphenyl)-4-yl-1H-imidazol-2-yl)methylcarbamate and 4-(2-{(IS)-1-

((butoxycarbonyl)amino)ethyl}-1H-imidazol-4-yl)-1,1'-biphenyl. Furthermore, these compounds render obvious applicants' instantly claimed invention as to those skilled in chemical art, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members. Also, the instant claimed compounds would have been obvious because one skilled in the art would have been motivated to prepare homologs of the compounds taught in the reference with the expectation of obtaining compounds which could be used in pharmaceutical compositions. Therefore, the instant claimed compounds would have been suggested to one skilled in the art. Lastly, nothing unobvious is seen in substituting the known claimed isomer for the structurally similar isomer since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. Since conflicting claim 44, anticipates or renders obvious applicants' instant claimed invention as the conflicting claims are directed to specific compounds within applicants' instantly claimed product claims or which render obvious applicants' instantly claimed product claims, applicants' product claims are therefore provisionally rejected on the ground of nonstatutory obviousness-type double patenting.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 35, 37, 45 and 46 rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/58934. WO 98/58934 discloses the compound 26.3 on page 94, 4-[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]-N-methyl-2-thiazolemethanamine.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 40 and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 02/10140.

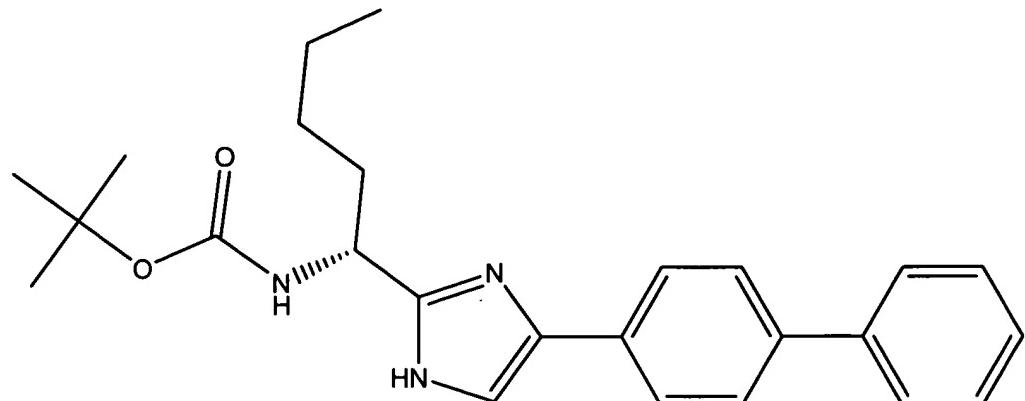
The applied reference has a common inventor with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

WO 02/10140 discloses imidazolyl derivatives of the formula (I), page 2.

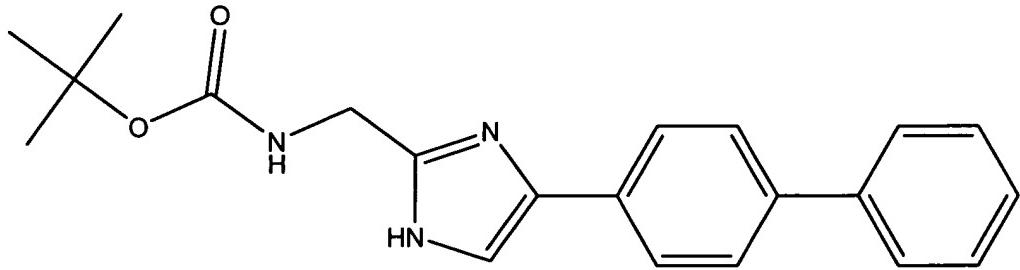
Pharmaceutical compositions are disclosed on page 20. Specific compounds which anticipate applicants' instant claims are found, for example, on page 327:



(R,S)-4-(2-{(tert-butoxycarbonyl)amino}pentyl)-1H-imidazol-4-yl)-1,1'-biphenyl

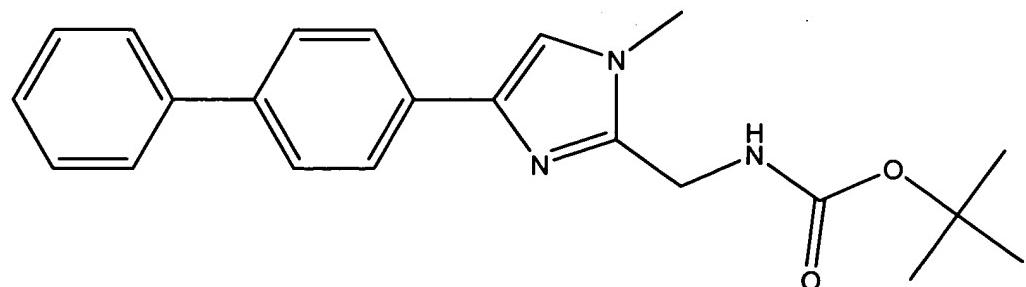
(example 13795);

page 333



4-(2-{(tert-butoxycarbonyl)amino}methyl)-1H-imidazol-4-yl)-1,1'-biphenyl

(example 13847);



4-(2-{(tert-butoxycarbonyl)amino}methyl)-1-methyl-1H-imidazol-4-yl)-1,1'-biphenyl

(example 13854);

page 334

4-(2-{((tert-butoxycarbonyl)methyl)amino)methyl}-1H-imidazol-4-yl)1,1'-biphenyl

(example 13856);

page 336

(R,S)-4-(2-{1-((tert-butoxycarbonyl)amino)heptyl}-1H-imidazol-4-yl)-1,1'-biphenyl

(example 13878);

4-(2-{(1S)-1-((tert-butoxycarbonyl)amino)propyl}-1H-imidazol-4-yl)-1,1'-biphenyl

(example 13880);

page 338

4-(2-{(IR)-1-((tert-butoxycarbonyl)amino)butyl}-1H-imidazol-4-yl)-1,1'-biphenyl

(example 13890);

page 341

4-(2-{(1S)-1-((butoxycarbonyl)amino)ethyl}-1H-imidazol-4-yl)-1,1'-biphenyl

(example 13920); and

4-(2-{(1R)-1-((butoxycarbonyl)amino)ethyl}-1H-imidazol-4-yl)-1,1'-biphenyl.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 43 and 48 are rejected under 35 U.S.C. 103(a) as being obvious over WO 02/10140.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the

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application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

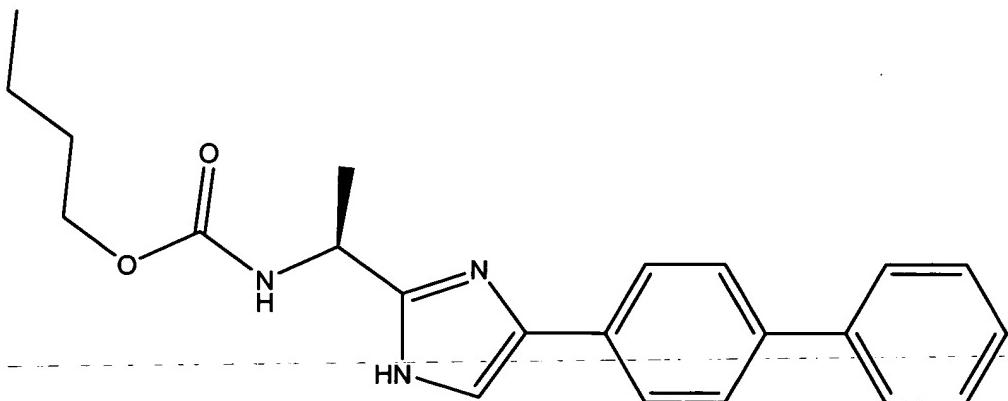
Determining the scope and contents of the prior art

WO 02/10140 discloses imidazolyl derivatives of the formula (I), page 2.

Pharmaceutical compositions are disclosed on page 20. Specific compounds which anticipate applicants' instant claims are found, for example, on page 327, 329, 333-339 and 341.

Ascertaining the differences between the prior art and the claims at issue

The difference between the prior art and the claims at issue is that the prior art claims are in a homologous series with the instant claimed compounds or are positional isomers of the instantly claimed compounds, see for example,



4(2-((1S)-1-((butoxycarbonyl)amino)ethyl)-1H-imidazol-4-yl)-1,1'biphenyl which differs

only in the position of the (butoxycarbonyl)amino group on the ethyl at position 2 of the imidazolyl.

Resolving the level of ordinary skill in the pertinent art

However, minus a showing of unobvious results, it would have been obvious to one of ordinary skill in the art at the time of the invention when faced with the prior art of WO 02/10140, to prepare applicants' instantly claimed compounds which differ from the prior art compounds by only as a positional isomer. The motivation would be the expectation of preparing additional compounds useful as antagonists of somatostatin receptors and for inhibiting the proliferation of Helicobacter pylori. Furthermore, to those skilled in chemical art, nothing unobvious is seen in substituting the known claimed isomer for the structurally similar isomer, as taught by WO 02/10140 since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. In re Norris, 84 USPQ 458 (1950).

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Rebecca Anderson
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

May 27, 2006